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① **Hollow fiber-type artificial lung.**

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**Description**

This invention relates to a hollow fiber-type artificial lung according to the first part of claim 1. Such artificial lung is used in extracorporeal circulation to remove carbon dioxide from blood and add oxygen to the blood.

Artificial lungs are broadly classified into those of porous and membrane type. The membrane artificial lung, such as of stacked membrane type, coil type or hollow fiber type, is widely recognized as being superior to the porous-type artificial lung in view of the fact that the blood conveyed through the lung undergoes less hemolysis, albumin degeneration, clotting and affixation, and as being extremely close to the human lung in terms of its operating mechanism. Nevertheless, because the membrane-type artificial lung possesses a number of disadvantages set forth hereinbelow, the artificial lung of porous type is that used most widely in open-heart surgery at the present time.

In order to obtain sufficient oxygenation with the membrane-type artificial lung currently available, it is required that the blood flow layer be reduced in thickness. This means a narrow blood flow passage and, hence, a large flow passage resistance. In consequence, it is not possible to achieve perfusion of the blood within the artificial lung by utilizing the head developed between the patient and the lung. Accordingly, as shown in Fig. 1, a blood circuit using the membrane-type artificial lung requires that a pump 2 be disposed on the inlet or venous side of the artificial lung, indicated at numeral 1. Numeral 3 denotes a blood reservoir, and 4 a heat exchanger. With the blood circuit shown in Fig. 1, however, the magnitude of the pressure adjacent the outlet of the pump 2 is greater than the sum of the pressure loss at the blood feeding catheter and the pressure loss of the artificial lung. The problem that results is an increase in the internal pressure of the circuit on the blood feeding side. A proposed solution to this problem, disclosed in JP-A-50-9299, is to pass the blood on the outer side of the hollow fibers. However, proposed arrangement has not put into practical use due to difficulties in removing air bubbles appeared in the blood in extracorporeal circuit. Further, there are difficulties in priming and the like to put the proposed artificial lung into practical use.

The specification of the abovementioned publication discloses a theoretical arrangement for passing oxygen gas on the outer side of hollow fibers, but the arrangement does not maximize the gas exchange capability of the hollow fibers. To obtain a practical system, not only must the gas exchange capability be improved, but the following factors must be taken into consideration. Specifically, through use of the blood reservoir 3 shown in Fig. 1, the extracorporeally circulating blood is temporarily stored so that any air bubbles entrained within the blood may be removed.

A divisional application (file-Np. 88 106 609.6) describes a hollow fiber type artificial lung comprising: an axially extended housing; a hollow fiber bundle having a multiplicity of hollow fibers accommodated within and along the axial direction of said housing, said hollow fibers forming blood channels between outer wall surfaces of neighbouring ones thereof, and being arranged within said housing in such a manner that neighbouring blood channels are brought into substantial communication; first and second supporting walls liquid-tightly supporting said hollow fibers at both end portions thereof within said housing; gas inlet means and, optionally, gas outlet means provided on an outer side of at least one of said first and second supporting walls and communicating with the hollow interior of said hollow fibers; said first and second supporting walls, the inner wall of said housing and the outer wall surfaces of said hollow fibers defining a blood chamber; blood inlet and outlet means communicating with said blood chamber; said blood chamber having a first blood flow passage at a portion adjacent said first supporting wall; said first blood flow passage communicating with said blood inlet means and surrounding said hollow fiber bundle circumferentially at the end portion retained by said first supporting wall; and a second blood flow passage at a portion adjacent said second supporting wall, said second blood flow passage communicating with said blood outlet means and surrounding said hollow fiber bundle circumferentially at the end portion retained by said second wall; and an intermediate portion providing constriction of the hollow fibers for reducing the cross-sectional area of the blood channels formed between neighbouring ones of said hollow fibers. In this artificial lung the inner surface of said housing in the vicinity of said blood inlet means is flared outwardly relative to the inner surface of the housing at the adjacent end of the intermediate portion thereof, thereby forming said first blood flow passage between the outer periphery of said hollow fiber bundle and the inner surface of said housing, said first blood flow passage being annular in shape.

A hollow fiber-type artificial lung according to the first part of claim 1 is already described in EP-A-0 048 943 and shown in Fig. 7 of this application.

Such a known artificial lung 11A, shown in Fig. 7, has projections P1, P2 projecting discontinuously in the direction of blood flow, these portions being located on the inner surface of a housing 15A defining a blood chamber 26A. With such an arrangement, the air to be vented during priming is entrapped by the projecting portions P1, P2, so that complete discharge of the air from the blood chamber 26A does not take place.

Accordingly, an object of the present invention is to provide a hollow fiber-type artificial lung which produces a blood flow capable of improving gas exchange efficiency per unit membrane area, which makes possible blood perfusion utilizing the head developed between the patient and

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the artificial lung, and which effectively removes air involved during priming and during use.

In accordance with the present invention, this object is achieved by a hollow fiber-type artificial lung as defined in claim 1.

The artificial lung comprises additionally a hollow fiber constricting portion for varying the cross-sectional area of the blood channels formed between neighbouring ones of said hollow fibers and gas venting means communicating with the interior of said blood chamber, said venting means being situated higher than said blood outlet means when the artificial lung is in use.

The above and other objects, features and advantages of the present invention will become more apparent from the following description when taken in conjunction with the accompanying drawings in which preferred embodiments of the present invention are shown by way of illustrative example.

Fig. 1 is a diagram of a blood circuit to which a prior-art membrane-type artificial lung is applied;

Fig. 2 is a diagram of a blood circuit to which the hollow fiber-type artificial lung of the present invention is applied;

Fig. 3 is a sectional view illustrating an embodiment of a hollow fiber-type artificial lung according to the present invention;

Fig. 4 is a sectional view taken along line IV—IV of Fig. 3;

Fig. 5 is a sectional view taken along line V—V of Fig. 3;

Fig. 6 is a sectional view taken along line VI—VI of Fig. 3;

Fig. 7 is a sectional view illustrating a hollow fiber-type artificial lung according to the prior art;

Fig. 8 is a sectional view showing the disposition of the hollow fiber-type artificial lung of the present invention during priming;

According to a first embodiment of the present invention, a hollow fiber-type artificial lung comprises an axially extended housing, a hollow fiber bundle having a multiplicity of hollow fibers accommodated within and along the axial direction of the housing, the hollow fibers forming blood channels between outer wall surfaces of neighboring ones thereof, and being arranged within the housing in such a manner that neighboring blood channels are brought into substantial communication, first and second supporting walls liquid-tightly supporting the hollow fibers at both end portions thereof within the housing, a gas inlet port and, optionally, a gas outlet port provided on an outer side of at least one of said first and second supporting walls and communicating with the hollow interior of the hollow fibers, the first and second supporting walls, the inner wall of the housing and the outer wall surfaces of the hollow fibers defining a blood chamber, blood inlet and outlet ports communicating with the blood chamber, the blood chamber having a first blood flow passage at a portion adjacent the first supporting wall, the first blood flow passage communicating with the blood inlet port and surrounding the hollow fiber

bundle circumferentially at the end portion retained by the first supporting wall, and a second blood flow passage at a portion adjacent the second supporting wall, the second blood flow passage communicating with the blood outlet port and surrounding the hollow fiber bundle circumferentially at the end portion retained by the second wall, an intermediate, hollow fiber constricting portion for continuously reducing the cross-sectional area of the blood channels formed between neighbouring ones of the hollow fibers with no local inwardly directed projection, and a gas venting port communicating with the interior of the blood chamber, the venting port being situated higher than the blood outlet port when the artificial lung is in use.

The gas venting port and the blood outlet port are provided at positions substantially symmetrical with respect to the axis of the housing. The second supporting wall has a concave portion on a side facing the second blood flow passage, and the gas venting port is provided in a side wall of the housing adjacent the concave portion of the second supporting wall. The hollow fibers are made of a microporous membrane.

The inner surface of the housing in the vicinity of the blood inlet port is flared outwardly relative to the inner surface of the housing at the adjacent end of the intermediate portion thereof, thereby forming the first blood flow passage between the outer periphery of the hollow fiber bundle and the inner surface of the housing, the first blood flow passage being annular in shape. Similarly, the inner surface of the housing in the vicinity of the blood outlet port is flared outwardly relative to the inner surface of the housing at the adjacent end of the intermediate portion thereof, thereby forming the second blood flow passage between the outer periphery of the hollow fiber bundle and the inner surface of the housing, the second blood flow passage also being annular in shape.

The flared inner surface of the housing in the vicinity of the blood inlet means is off centered with respect to the hollow fiber bundle so as to increase the distance between the blood inlet means and the hollow fiber bundle, thereby enlarging the flow area of the first blood flow passage facing the blood inlet means. Likewise, the flared inner surface of the housing in the vicinity of the blood outlet means is off centered with respect to the hollow fiber bundle so as to increase the distance between the blood outlet means and the hollow fiber bundle, thereby enlarging the flow area of the second blood flow passage facing the blood outlet means.

The gas venting port includes a detachable filter permeable to gas but impermeable to bacteria.

Reference will now be had to Figs. 2 through 5 to describe the artificial lung in detail. Fig. 2 is a diagram of a blood circuit to which the hollow fiber-type artificial lung of the present invention is applied, Fig. 3 is a sectional view illustrating an embodiment of a hollow fiber-type artificial lung according to the present invention, Fig. 4 is a sectional view taken along line IV—IV of Fig. 3,

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Fig. 5 is a sectional view taken along line V—V of Fig. 3, and Fig. 6 is a sectional view taken along line VI—VI of Fig. 3.

As shown in Fig. 2, a blood circuit to which the present invention is applied has an artificial lung 11, a blood reservoir 12, a pump 13 and a heat exchanger 14 through which blood is passed in the order mentioned.

As illustrated in Figs. 3 through 6, the artificial lung 11 includes a tubular housing 15 accommodating a bundle 17 of hollow fibers 16. The ends of the hollow fibers 16 are retained liquid tightly within the housing 15 via walls 18, 19. A header 20 is attached to one end portion of the housing 15, and a header 21 to the other end thereof. The inner side of the header 20 and the wall 18 define a gas inlet chamber 22 communicating with the space within each of the hollow fibers 16. The inner side of the header 21 and the wall 19 define a gas outlet chamber 24 similarly communicating with the space within each of the hollow fibers. The header 21 is formed to include a gas outlet port 25, and the header 20 is formed to include a gas inlet port 23. Thus, a gas such as oxygen or air supplied from the gas inlet port 23 is capable of being passed through the interior of the hollow fibers 16. It should be noted that the header 21, and hence the gas outlet chamber 24 and gas outlet port 25, is not particularly essential, for an arrangement can be adopted wherein the gas exiting from the hollow fibers 16 is released directly into the atmosphere.

The walls 18, 19, the inner surface of the housing 15, and the outer peripheral surface of the hollow fibers 16 define a blood chamber 26. Formed at the respective ends of the housing 15 in the side thereof are a blood inlet port 27 and a blood outlet port 28, each of which communicates with the blood chamber 26. More specifically, the outer walls of adjacent hollow fibers 16 define channels through which the entrant blood may flow, and neighbouring channels communicate with one another owing to the clustered hollow fiber bundle. In consequence, the streams of blood flowing through these channels interfere with one another, causing the blood to flow in a turbulent manner. This makes it possible to achieve a turbulent blood flow at the periphery of the hollow fibers 16 within the blood chamber 26.

The inner surface of the housing 15 at the portion where the blood inlet port 27 is provided is flared outwardly relative to the inner surface of the housing at the intermediate portion thereof, thereby forming an annular blood flow passage 29 between the outer periphery of the hollow fiber bundle 17 and the inner surface of the housing at the flared end, as shown in Fig. 5. This makes it possible for the entrant blood to be distributed to each of the hollow fibers 16 smoothly from the entire outer periphery of the bundle 17 facing the blood flow passage 29. Further, as shown in Fig. 5, the flared inner surface of the housing 15 is off centered with respect to the hollow fiber bundle 17 so as to increase the distance between the blood inlet port 27 and the bundle, thereby

enlarging the flow area of that part of the blood flow passage 29 facing the blood inlet port 27. Thus, the flow passage area of the blood flow passage 29 gradually diminishes with an increase in distance from the blood inlet port 27, so that the blood from the blood flow passage 29 is distributed in a uniform amount circumferentially of the hollow fiber bundle 17. This makes it possible for the flow rate of the blood traveling axially of the housing 15 within the blood chamber 26 to be uniformized in relation to the circumferential direction of the hollow fiber bundle 17.

The inner surface of the housing 15 at the portion where the blood outlet port 28 is provided is flared outwardly relative to the inner surface of the housing at the intermediate portion thereof, thereby forming an annular blood flow passage 30 between the outer periphery of the hollow fiber bundle 17 and the inner surface of the housing at this flared end, as shown in Fig. 6. The blood enveloping each of the hollow fibers 16 will therefore flow from the entire outer periphery of the bundle 17, which is facing the blood flow passage 30, into the abovementioned blood channels, and will proceed toward the blood outlet port 28 while mixing of the blood flowing through a plurality of the channels takes place. Further, as shown in Fig. 6, the flared inner surface of the housing 15 at the blood outlet end thereof is off centered with respect to the hollow fiber bundle 17 so as to increase the distance between the blood outlet port 28 and the bundle, thereby enlarging the flow area of that part of the blood flow passage 30 facing the blood outlet port 28. Thus, the flow passage area of the blood flow passage 30 gradually diminishes with an increase in distance from the blood outlet port 28, so that the amount of blood introduced to the blood flow passage 30 is uniformized circumferentially of the hollow fiber bundle 17. This makes it possible for the flow rate of the blood traveling axially of the housing 15 within the blood chamber 26 to be uniformized in relation to the circumferential direction of the hollow fiber bundle 17.

The housing 15 is shaped such that its inner diameter has a minimum value at the mid portion of the housing axially thereof and a gradually larger value as the ends of the housing are approached. Thus, the housing 15 narrows or tapers towards its center from both ends to constrict the outer periphery of the hollow fiber bundle 17 at the central portion thereof in the axial direction. Owing to the constriction of the fiber bundle 17 produced by the tapered shape of the housing 15, a uniform flow of blood through a transverse cross section of the fiber bundle 17 is obtained, and the flow speed varies along the axis of the bundle to promote a turbulent flow condition. This makes it possible to improve gas exchange efficiency. It will be appreciated from Figs. 3 and 4 that the centrally tapered inner wall of the housing 15 and the inner walls of the housing defining the blood flow passages 29, 30 form a continuous inner wall surface flaring out-

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wardly from the central portion of the housing using. This configuration assures that air, which is to be purged from the housing 15 during priming, will travel along the inner wall surface of the housing and exit from a gas venting port 31, described later, without residing in the blood chamber 26. Alternatively, the inner wall of the housing 15 may be flared linearly from, say, the end having the blood inlet port 27 to the end having the blood outlet port 28.

Each of the hollow fibers 16 consists of a microporous membrane. More specifically, each hollow fiber comprises a porous polyolefin resin such as polypropylene or polyethylene, with polypropylene being preferred. In this case, the hollow fibers 16 have a multiplicity of small pores or holes interconnecting the inside and outside of the fiber wall. The hollow fiber has an inner diameter of about 100 to 1,000  $\mu$ , a wall thickness of about 10 to 500 and preferably 10 to 50  $\mu$ , and a porosity in the range of about 20 to 80 percent. With hollow fibers 16 of this kind, membrane resistance to gas flow may be reduced and an excellent gas exchange performance obtained because the gas flow occurs as a volume flow. It should be noted that the hollow fibers 16 need not necessarily consist of a microporous membrane. For example, use can be made of a silicone membrane that permits travel of a gas by dissolution or diffusion.

The packing rate of the housing 15 having hollow fibers of the foregoing type is as specified by the following formula:

$$\text{packing rate (\%)} = \frac{\text{total cross-sectional area of fibres}}{\text{housing cross-sectional area}} \times 100$$

More specifically,

$$\text{packing rate } P(\%) = \frac{(1/2) \pi r^2 n}{(1/4) \pi a^2} \times 100$$

where  $r$  represents the outer diameter of the hollow fibers,  $n$  the number of hollow fibers enclosed within the housing, and  $a$  the inner diameter of the housing. The preferred packing rate at the end portions of the housing, namely at the portions of maximum diameter, is 20 to 50%. The preferred packing rate at the centrally constricted portion of the housing is from 1.2 to 4 times the packing rate at the housing end portions. If the packing rate at the housing end portions is less than 20%, there is little surface contact with the outer wall of the hollow fibers and the blood flow is too linear. The result is an unsatisfactory gas exchange performance. If the packing rate at the housing end portions is greater than 50%, on the other hand, the flow of blood is impeded, giving rise to an excessive pressure loss. In a case where the centrally constricted portion is provided, it is necessary to

increase the packing density at the constricted portion by at least 1.2 times. A figure below 1.2 times will make it difficult for the blood to flow in the desired turbulent manner, while a packing ratio greater than four times end portion packing ratio, or in excess of 80%, will give rise to an undesirable pressure loss.

The hollow fiber-type artificial lung most preferred has 40,000 hollow fibers, each having an outer diameter of 250  $\mu$ m, enclosed within a housing the inner diameter whereof is 80.0 mm at the end portions and 64.0 mm at the constricted portion thereof. The packing rate is 39.1% at the end portions and 61.0% at the constricted portion.

The walls 18, 19 are formed by a centrifugal injection process in the following manner. First, a multiplicity of the hollow fibers 16, which are longer than the housing 15, are prepared, both open ends of the fibers are plugged with a highly viscous resin, and the fibers are then placed side by side within the housing 15. Thereafter, with both ends of the hollow fibers completely covered, a polymeric potting agent is poured in from both ends of the housing 15 while the housing is being rotated about a center of rotation decided by the longitudinal direction of the housing, under a condition in which the central axis of the housing is situated in the direction of the radius of rotation. After the poured resin has hardened, the outer faces of the resin are cut off by means of a sharp blade to expose both open ends of the hollow fibers 16. This completes the formation of the walls 18, 19. As will be understood from Figs. 3 and 4, the sides of the walls 18, 19 facing the blood chamber 26 define cylindrical concavities.

The housing 15 is provided with a gas venting port 31 communicating with the blood chamber 26, the port being situated higher than the blood outlet port 28 when the artificial lung is in use. The gas venting port 31 is fitted with a detachable filter 32 permeable to air but not to bacteria. The filter 32 is removed during priming and reattached after priming and serves to prevent bacterial contamination of the artificial lung 11 during the venting of air evolved when the artificial lung is used.

During priming, the gas venting port 31 allows air to escape from the interior of the blood circuit and artificial lung 11, which air is displaced by a filling liquid such as a physiologic saline. Following the removal of air, the port 31 is plugged to form a hermetic seal.

The gas venting port 31 and blood outlet port 28 are provided at positions symmetrical with respect to the axis of the housing 15. During priming, as shown in Fig. 8, the central axis of the artificial lung 11 is tilted in a plane which contains both the gas venting port 31 and blood outlet port 28, whereby the gas venting port 31 is placed higher than the blood outlet port 28 to assure and facilitate the discharge of air. The gas venting port 31 is located in the side wall of the housing 15 at a point adjacent the concave surface of the wall 18, as best shown in Fig. 4, so as to communicate

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with the uppermost part of the blood chamber 26. This makes possible the complete discharge of air during priming, as well as the complete discharge of air which occurs when the artificial lung is used, as when air that remains in the blood circuit connecting joints flows into the artificial lung during use. It should be noted that the gas venting port may be so provided as to penetrate the center of the wall 18.

The operation of the artificial lung shown in Figs. 3 through 6 will now be described. The artificial lung is for use in, e.g., open-heart surgery, and is installed in a blood circulating circuit of the kind shown in Fig. 2. Ordinarily, blood is extracted at a flow rate of 4 l/min.

First, prior to introducing blood into the artificial lung 11, physiologic saline mixed with heparin is introduced from the blood inlet port 27 to exclude all air from the blood chamber 26 within the artificial lung 11. During this process, a tube communicating with the blood reservoir will be connected to the gas venting port 31, from which the filter 32 has been removed, and the blood outlet port 28 is either connected to a tube in the same manner as the gas venting port 31, or otherwise sealed by means of a cap or the like. Following the complete purging of the air from the interior of the artificial lung 11, the filter 32 is fitted into the gas venting port 31 which is then sealed by means of a cap, not shown. Blood is introduced from the patient into the artificial lung 11 from the blood inlet port 27 at a predetermined head (on the order of 1 m). The entrant blood impinges upon the outer walls of the hollow fibers 16 near the blood inlet port 27 and flows into the annular blood flow passage 29 defined within the artificial lung. Owing to the force of gravity and the 1 m head, the blood rises within the blood chamber 26. As this proceeds, an exchange is effected between the carbon dioxide contained in the blood and oxygen, which enters from the gas inlet port 23 through the hollow fibers 16. The oxygenated blood flows out of the blood outlet port 28 through the blood flow passage 30, is held in the reservoir 12 (Fig. 2) and then, under the influence of the blood feeding pump 13, is heated or cooled by the heat exchanger 14 before being fed back into the patient.

Any air that appears in the artificial lung 11 during the feeding of the blood, which air is primarily the result of residual air from the tube connections of the blood circuit, flows in from the blood inlet port 27 together with the entering blood, rises within the blood chamber 26 and collects in the concave portion of the wall 18 at the upper end of the blood flow path 30. The collected air is released to the outside through the filter 32 by removing the cap from the gas venting port 31. At such time the artificial lung 11 preferably is tilted, as shown in Fig. 8, to bring the gas venting port 31 to a position higher than that of the blood outlet port 28.

The actions and effects of the artificial lung 11 shown in Figs. 3 through 6 and in Fig. 8 will now be set forth.

As described hereinabove, the hollow fiber-type artificial lung 11 of the invention comprises an axially extended housing, a hollow fiber bundle having a multiplicity of hollow fibers accommodated within and along the axial direction of the housing, the hollow fibers forming blood channels between outer wall surfaces of neighboring ones thereof, and being arranged within the housing in such a manner that neighboring blood channels are brought into substantial communication, first and second walls liquid-tightly supporting the hollow fibers at both end portions thereof within the housing, a gas inlet port provided on an outer side of the first or second wall and communicating with the hollow interior of the hollow fibers, the first and second walls, the inner wall of the housing and the outer wall surfaces of the hollow fibers defining a blood chamber, blood inlet and outlet ports communicating with the blood chamber, the blood chamber having a first blood flow passage at a portion adjacent the first wall, the first blood flow passage communicating with the blood inlet port and surrounding the hollow fiber bundle circumferentially at the end portion retained by the first wall, and a second blood flow passage at a portion adjacent the second wall, the second blood flow passage communicating with the blood outlet port and surrounding the hollow fiber bundle circumferentially at the end portion retained by the second wall, a hollow fiber constricting portion for varying the cross sectional area of the blood channels formed between neighboring ones of the hollow fibers, and a gas venting port communicating with the interior of the blood chamber, the venting port being situated higher than the blood outlet port when the artificial lung is in use. Owing to such construction, gas exchange takes place while the blood is flowing in a turbulent state, making it possible to improve the gas exchange performance per unit membrane area. In addition, the blood flow resistance interiorly of the blood chamber does not take on a large magnitude, so that perfusion of the blood may be achieved owing to the head developed between the patient and the artificial lung.

Further, since the gas venting port and the blood outlet port are provided at positions substantially symmetrical with respect to the axis of the housing, air can be discharged from the artificial lung reliably and with ease during priming by placing the gas venting port higher than the blood outlet port, this being accomplished by tilting the central axis of the artificial lung in a plane containing the gas venting port and gas outlet port. The gas venting port is provided in a side wall of the housing adjacent the concave portion of the second wall. Consequently, the gas venting port communicates with the uppermost end of the blood chamber, making it possible to completely discharge air during priming, as well as air which occurs during use. The hollow fibers are made of a microporous membrane to reduce the resistance of the membrane to traveling gases, and to enhance the gas exchange performance.

In the artificial lung, the inner surface of the

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housing where the blood inlet port is provided is flared outwardly relative to the inner surface of the housing at the intermediate portion thereof, thereby forming the annular first blood flow passage between the outer periphery of the hollow fiber bundle and the inner surface of the housing. This makes it possible for the entrant blood to be distributed to each of the hollow fibers smoothly from the entire outer periphery of the bundle facing the first blood flow passage. The inner surface of the housing where the blood outlet port is provided is flared outwardly relative to the inner surface of the housing at the intermediate portion thereof, thereby forming the annular second blood flow passage between the outer periphery of the hollow fiber bundle and the inner surface of the housing. This makes it possible for the blood enveloping each of the hollow fibers to be introduced smoothly from the entire outer periphery of the fiber bundle facing the second blood flow passage, into the blood outlet port.

The flared inner surface of the housing in the vicinity of the blood inlet port is off centered with respect to the hollow fiber bundle so as to increase the distance between the blood inlet port and the hollow fiber bundle, thereby enlarging the flow area of the first blood flow passage facing the blood inlet port. As a result, the blood from the blood flow passage is distributed in a uniform amount circumferentially of the hollow fiber bundle, making it possible for the flow rate of the blood traveling axially of the housing within the blood chamber to be uniformized in relation to the circumferential direction of the hollow fiber bundle. Similarly, the flared inner surface of the housing in the vicinity of the blood outlet port is off centered with respect to the hollow fiber bundle so as to increase the distance between the blood outlet port and the hollow fiber bundle, thereby enlarging the flow area of the second blood flow passage facing the blood outlet port. As a result, the amount of blood introduced to the blood flow passage is uniformized circumferentially of the hollow fiber bundle, making it possible for the flow rate of the blood traveling axially of the housing within the blood chamber to be uniformized in relation to the circumferential direction of the hollow fiber bundle.

Further, the gas venting port of the artificial lung includes a detachable filter permeable to gas but impermeable to bacteria. This prevents bacterial contamination of the artificial lung when venting air evolved during use of the artificial lung.

#### Claims

1. A hollow fiber-type artificial lung comprising:

- an axially extended housing (15);
- a hollow fiber bundle (17) having a multiplicity of hollow fibers (16) accommodated within and along the axial direction of said

housing, said hollow fibers forming blood channels between outer wall surfaces of neighbouring ones thereof, and being arranged within said housing in such a manner that neighbouring blood channels are brought into substantial communication;

—first and second supporting walls (18, 19) liquid-tightly supporting said hollow fibers at both end portions thereof within said housing;

—gas inlet means (22) and, optionally, gas outlet means (21) provided on an outer side of at least one of said first and second supporting walls (18, 19) and communicating with the hollow interior of said hollow fibers (16);

—said first and second supporting walls (18, 19), the inner wall of said housing (15) and the outer wall surfaces of said hollow fibers (16) defining a blood chamber (26);

—blood inlet and outlet means (27, 28) communicating with said blood chamber (26);

—said blood chamber (26) having a first blood flow passage (29) at a portion adjacent said first supporting wall (19), said first blood flow passage communicating with said blood inlet means (27) and surrounding said hollow fiber bundle (17) circumferentially at the end portion retained by said first supporting wall (19), and a second blood flow passage (30) at a portion adjacent said second supporting wall (18), said second blood flow passage (30) communicating with said blood outlet means (28) and surrounding said hollow fiber bundle (17) circumferentially at the end portion retained by said second wall (18);

—an intermediate portion providing constriction of the hollow fibers for reducing the cross-sectional area of the blood channels formed between neighbouring ones of said hollow fibers (16);

characterized in that

—the cross-sectional area of the housing within the intermediate portion thereof continuously reduces from each end thereof towards the respective opposite end such that the inner surfaces defining said reducing cross-sectional areas meet and form a minimum cross-sectional area of the housing providing maximum constriction of the hollow fiber bundle with no local inwardly directed projection, and in that

—gas venting means (31) communicates with the interior of said blood chamber (26);

—said venting means being situated higher than said blood outlet means (28) when the artificial lung is in use.

2. The artificial lung according to claim 1, wherein said gas venting means (21) and said blood outlet means (28) are provided at positions substantially symmetrical with respect to the axis of said housing (15).

3. The artificial lung according to claim 1, wherein said second supporting wall (18) has a concave portion on a side facing said second blood flow passage (30), and wherein said gas venting means (31) is provided in a side wall of

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said h using adjacent the c ncave portion of said second supporting wall (18).

4. The artificial lung according t claim 1, wherein said hollow fibers (16) are made of a microporous membrane.

5. The artificial lung according to claim 1, wherein the inner surface of said housing (15) in the vicinity of said blood inlet means (27) is flared outwardly relative to the inner surface of the housing at the adjacent end of the intermediate portion thereof, thereby forming said first blood flow passage (29) between the outer periphery of said hollow fiber bundle (17) and the inner surface of said housing (15), said first blood flow passage (26) being annular in shape.

6. The artificial lung according to claim 1, wherein the inner surface of said housing (15) in the vicinity of said blood outlet means (28) is flared outwardly relative to the inner surface of the housing at the adjacent end of the intermediate portion thereof, thereby forming said second blood flow passage (30) between the outer periphery of said hollow fiber bundle (17) and the inner surface of said housing, said second blood flow passage (28) being annular in shape.

7. The artificial lung according to claim 5, wherein the flared inner surface of said housing (15) in the vicinity of said blood inlet means (27) is off centered with respect to said hollow fiber bundle (17) so as to increase the distance between said blood inlet means and said hollow fiber bundle, thereby enlarging the flow area of said first blood flow passage facing said blood inlet means.

8. The artificial lung according to claim 6, wherein the flared inner surface of said housing (15) in the vicinity of said blood outlet means (28) is off centered with respect to said hollow fiber bundle (17) so as to increase the distance between said blood outlet means (28) and said hollow fiber bundle (17), thereby enlarging the flow area of said second blood flow passage facing said blood outlet means.

9. The artificial lung according to claim 6, wherein said gas venting means comprises a gas venting port (31) having a detachable filter permeable to gas and impermeable to bacteria.

#### Patentansprüche

1. Künstliche Lunge vom Hohlfasertyp mit:
  - einem sich axial erstreckenden Gehäuse (15);
  - einem Hohlfaserbündel (17) mit einer Vielzahl von darin aufgenommenen und sich längs der Axialrichtung des Gehäuses erstreckenden Hohlfasern (16), die Blutkanäle zwischen Außenwandflächen benachbarter Hohlfasern bilden und derart im Gehäuse angeordnet sind, daß benachbarte Blutkanäle in eine wesentliche Verbindung gebracht sind;
  - ersten und zweiten Trägerwänden (18, 19), die flüssigkeitsdicht die Hohlfasern an beiden Endteilen hiervon innerhalb des Gehäuses tragen;
  - einer Gaseinlaßeinrichtung (22) und ggf.

einer Gasauslaßeinrichtung (21), die auf ein r Außenseite w nigstens einer der ersten und zw iten Trägerwand (18, 19) vorgesehen sind und mit dem hohlen Inneren der Hohlfasern (16) in Verbindung stehen;

—wobei die ersten und zweiten Trägerwände (18, 19), die Innenwand des Gehäuses (15) und die Außenwandflächen der Hohlfasern (16) eine Blutkammer (26) festlegen.

—Bluteinlaß- und -auslaßeinrichtungen (27, 28), die mit der Blutkammer (26) in Verbindung stehen;

—wobei die Blutkammer (26) einen ersten Blutströmungsdurchgang (29) an einem Teil neben der ersten Trägerwand (19), wobei der erste Blutströmungsdurchgang mit der Bluteinlaßeinrichtung (27) in Verbindung steht und das Hohlfaserbündel (17) umfangsmäßig an dem durch die erste Trägerwand (19) zurückgehaltenen Endteil umgibt, und einen zweiten Blutströmungsdurchgang (30) an einem Teil neben der zweiten Trägerwand (18), wobei der zweite Blutströmungsdurchgang (13) mit der Blutauslaßeinrichtung (28) in Verbindung steht und das Hohlfaserbündel (17) umfangsmäßig an dem durch die zweite Wand (18) zurückgehaltenen Endteil umgibt, aufweist;

—einem Mittelteil, der eine Einschnürung der Hohlfasern liefert, um die Querschnittsfläche der zwischen benachbarten Hohlfasern (16) gebildeten Blutkanäle zu vermindern; dadurch gekennzeichnet, daß

—die Querschnittsfläche des Gehäuses innerhalb des Zwischenteiles hiervon sich kontinuierlich von jedem Ende hiervon auf das jeweilige entgegengesetzte Ende derart vermindert, daß die Innenflächen, die die sich vermindern den Querschnittsflächen festlegen, eine Mindestquerschnittsfläche des Gehäuses erfüllen und bilden, die eine maximale Einschnürung des Hohlfaserbündels mit keinem lokal nach innen gerichteten Vorsprung hervorruft, und daß

—eine Gasbelüftungseinrichtung (31) mit dem Inneren der Blutkammer (26) in Verbindung steht, wobei die Belüftungseinrichtung höher als die Blutauslaßeinrichtung (28) liegt, wenn die künstliche Lunge in Gebrauch ist.

2. Künstliche Lunge nach Anspruch 1, bei der die Gasbelüftungseinrichtung (21) und die Blutauslaßeinrichtung (28) an bezüglich der Achse des Gehäuses (15) im wesentlichen symmetrischen Stellen vorgesehen sind.

3. Künstliche Lunge nach Anspruch 1, bei der die zweite Trägerwand (18) einen konkaven Teil auf einer dem zweiten Blutströmungsdurchgang (30) gegenüberliegenden Seite hat und bei der die Gasbelüftungseinrichtung (31) in einer Seitenwand des Gehäuses neben dem konkaven Teil der zweiten Trägerwand (18) vorgesehen ist.

4. Künstliche Lunge nach Anspruch 1 bei der die Hohlfasern (16) aus einer mikroporösen Membran herg stellt sind.

5. Künstliche Lunge nach Anspruch 1 bei der die Innenfläch des Gehäuses (15) in der Nähe der Bluteinlaßeinrichtung (27) nach außen bezüglich der Innenfläche des Gehäuses am benachbart n



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Ende des Zwischenteiles hiervon aufgebauscht ist, um so den ersten Blutströmungsdurchgang (29) zwischen dem Außenrand des Hohlaserbündels (17) und der Innenfläche des Gehäuses (15) zu bilden, wobei der erste Blutströmungsdurchgang (26) ringförmig ist.

6. Künstliche Lunge nach Anspruch 1, bei der die Innenfläche des Gehäuses (15) in der Nähe der Blutaussaßeinrichtung (28) bezüglich der Innenfläche des Gehäuses an dem benachbarten Ende des Zwischenteiles hiervon aufgebauscht ist, um dadurch den zweiten Blutströmungsdurchgang (30) zwischen dem Außenumfang des Hohlaserbündels (17) und der Innenfläche des Gehäuses zu bilden, wobei der zweite Blutströmungsdurchgang (28) ringförmig ist.

7. Künstliche Lunge nach Anspruch 5, bei der die aufgebauchte Innenfläche des Gehäuses (15) in der Nähe der Bluteinlaßeinrichtung (27) aus der Mitte bezüglich des Hohlaserbündels (17) versetzt ist, um so den Abstand zwischen der Bluteinlaßeinrichtung und dem Hohlaserbündel zu vergrößern, wodurch die Strömungsfläche des ersten Blutströmungsdurchgangs gegenüber der Bluteinlaßeinrichtung erweitert ist.

8. Künstliche Lunge nach Anspruch 6, bei der die aufgebauchte Innenfläche des Gehäuses (15) in der Nähe der Blutaussaßeinrichtung (28) aus der Mitte bezüglich des Hohlaserbündels (17) versetzt ist, um so den Abstand zwischen der Blutaussaßeinrichtung (28) und dem Hohlaserbündel (17) zu vergrößern, wodurch die Strömungsfläche des zweiten Blutströmungsdurchgangs gegenüber der Blutaussaßeinrichtung erweitert ist.

9. Künstliche Lunge nach Anspruch 6, bei der die Gasbelüftungseinrichtung eine Gasbelüftungsöffnung (31) mit einem lösbaren Filter hat, das für Gas durchlässig und für Bakterien undurchlässig ist.

#### Revendications

1. Poumon artificiel du type à fibres creuses comprenant:

- une enveloppe s'étendant axialement (15);
- un faisceau de fibres creuses (17) comportant une multiplicité de fibres creuses (16) logées à l'intérieur de ladite enveloppe et suivant sa direction axiale, lesdites fibres creuses formant des conduits de sang entre les surfaces de paroi externe de fibres adjacentes, et disposées à l'intérieur de ladite enveloppe de telle sorte que les conduits de sang adjacents soient mis sensiblement en communication les uns avec les autres;
- des première et seconde parois de support (18, 19) supportant lesdites fibres creuses de manière étanche au liquide aux deux parties d'extrémité de ces dernières à l'intérieur de ladite enveloppe;

- un moyen d'admission de gaz (22) et, optionnellement, un moyen de sortie de gaz (21) prévus sur un côté externe d'au moins une desdites première et seconde parois de support (18, 19) et communiquant avec l'intérieur creux desdites fibres creuses (16);
- lesdites première et seconde parois de sup-

port (18, 19), la paroi interne de ladite enveloppe (15) et les surfaces de paroi externe desdites fibres creuses (16) définissant une chambre à sang (26);

- des moyens d'admission et de sortie de sang (27, 28) en communication avec ladite chambre à sang (26);

- ladite chambre à sang (26) comportant un premier passage d'écoulement de sang (29) situé à une partie adjacente à la première paroi de support (19), ledit premier passage d'écoulement de sang étant en communication avec lesdits moyens d'admission de sang (27) et entourant ledit faisceau de fibres creuses (17) circonférentiellement à la partie d'extrémité retenue par ladite première paroi de support (19), et un second passage d'écoulement de sang (30) situé à une partie adjacente à ladite seconde paroi de support (18), ledit second passage d'écoulement de sang (30) étant en communication avec lesdits moyens de sortie de sang (28) et entourant ledit faisceau de fibres creuses (17) circonférentiellement à la partie d'extrémité retenue par ladite seconde paroi (18).

- une partie intermédiaire assurant la constriction des fibres creuses afin de réduire la section transversale des conduits de sang formés entre celles desdites fibres creuses (16) qui sont adjacentes;
- caractérisé en ce que.

- la section transversale de l'enveloppe à l'intérieur de sa partie intermédiaire diminue progressivement à partir de chacune de ses extrémités en allant vers l'extrémité opposée respective si bien que les surfaces internes définissant lesdites sections transversales progressivement réduites se rencontrent et forment une section transversale minimale de l'enveloppe assurant une constriction maximale du faisceau de fibres creuses sans protubérance locale orientée vers l'intérieur, et en ce que

- un moyen de dégagement de gaz (31) communique avec l'intérieur de ladite chambre à sang (26), ledit moyen de dégagement étant placé plus haut que ledit moyen de sortie de sang (28) lorsque le poumon artificiel est en service.

2. Poumon artificiel selon la revendication 1, dans lequel ledit moyen de dégagement de gaz (21) et ledit moyen de sortie de sang (28) sont prévus en des emplacements sensiblement symétriques par rapport à l'axe de ladite enveloppe (15).

3. Poumon artificiel selon la revendication 1, dans lequel ladite seconde paroi de support (18) comporte une partie concave sur un côté situé face audit second passage d'écoulement de sang (30), et dans lequel ledit moyen de dégagement de gaz (31) est prévu dans une paroi latérale de ladite enveloppe adjacente à la partie concave de ladite seconde paroi de support (18).

4. Poumon artificiel selon la revendication 1, dans lequel lesdites fibres creuses (16) sont réalisées en une membrane microporeuse.

5. Poumon artificiel selon la revendication 1, dans lequel la surface interne de ladite enveloppe (15) à proximité dudit moyen d'admission de sang (27) s'évase vers l'extérieur par rapport à la surface interne de l'enveloppe à l'extrémité adjacente de la

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partie intermédiaire de ladite enveloppe, formant ainsi le premier passage d'écoulement de sang (29) entre la périphérie externe dudit faisceau de fibres creuses (17) et la surface interne de ladite enveloppe (15), ledit premier passage d'écoulement de sang (26) étant de forme annulaire.

6. Poumon artificiel selon la revendication 1, dans lequel la surface interne de ladite enveloppe (15) à proximité dudit moyen de sortie de sang (28) s'évase vers l'extérieur par rapport à la surface interne de l'enveloppe à l'extrémité adjacente de la partie intermédiaire de ladite enveloppe, formant ainsi ledit second passage d'écoulement de sang (30) entre la périphérie externe dudit faisceau de fibres creuses (17) et la surface interne de ladite enveloppe, ledit second passage d'écoulement de sang (28) étant de forme annulaire.

7. Poumon artificiel selon la revendication 5, dans lequel la surface interne évasée de ladite enveloppe (15) à proximité dudit moyen d'admission de sang (27) est excentrée par rapport audit

faisceau de fibres creuses (17) afin d'augmenter la distance séparant ledit moyen d'admission de sang et ledit faisceau de fibres creuses, ce qui agrandit la superficie d'écoulement dudit premier passage d'écoulement de sang en regard dudit moyen d'admission de sang.

8. Poumon artificiel selon la revendication 6, dans lequel la surface interne évasée de ladite enveloppe (15) à proximité dudit moyen de sortie de sang (28) est excentrée par rapport audit faisceau de fibres creuses (17) afin d'augmenter la distance séparant ledit moyen de sortie de sang (28) et ledit faisceau de fibres creuses (17), ce qui agrandit la superficie d'écoulement dudit second passage d'écoulement de sang en regard dudit moyen de sortie de sang.

9. Poumon artificiel selon la revendication 6, dans lequel ledit moyen de dégagement de gaz comporte un orifice de dégagement de gaz (31) muni d'un filtre démontable perméable au gaz et imperméable aux bactéries.

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FIG. 1

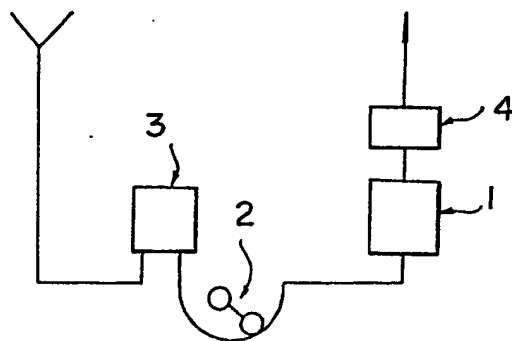


FIG. 2

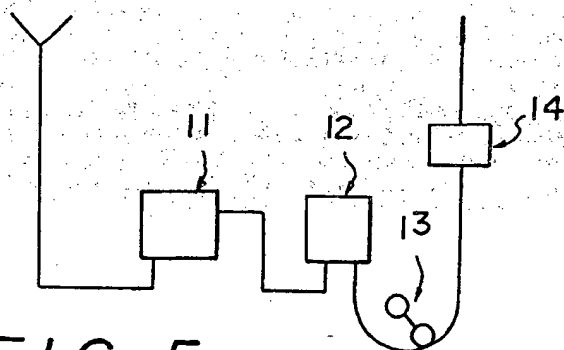
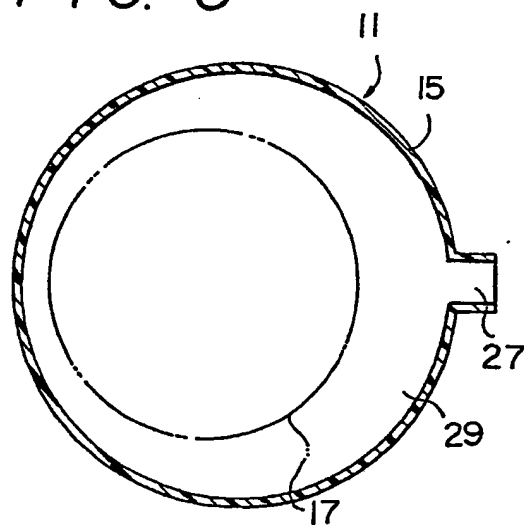
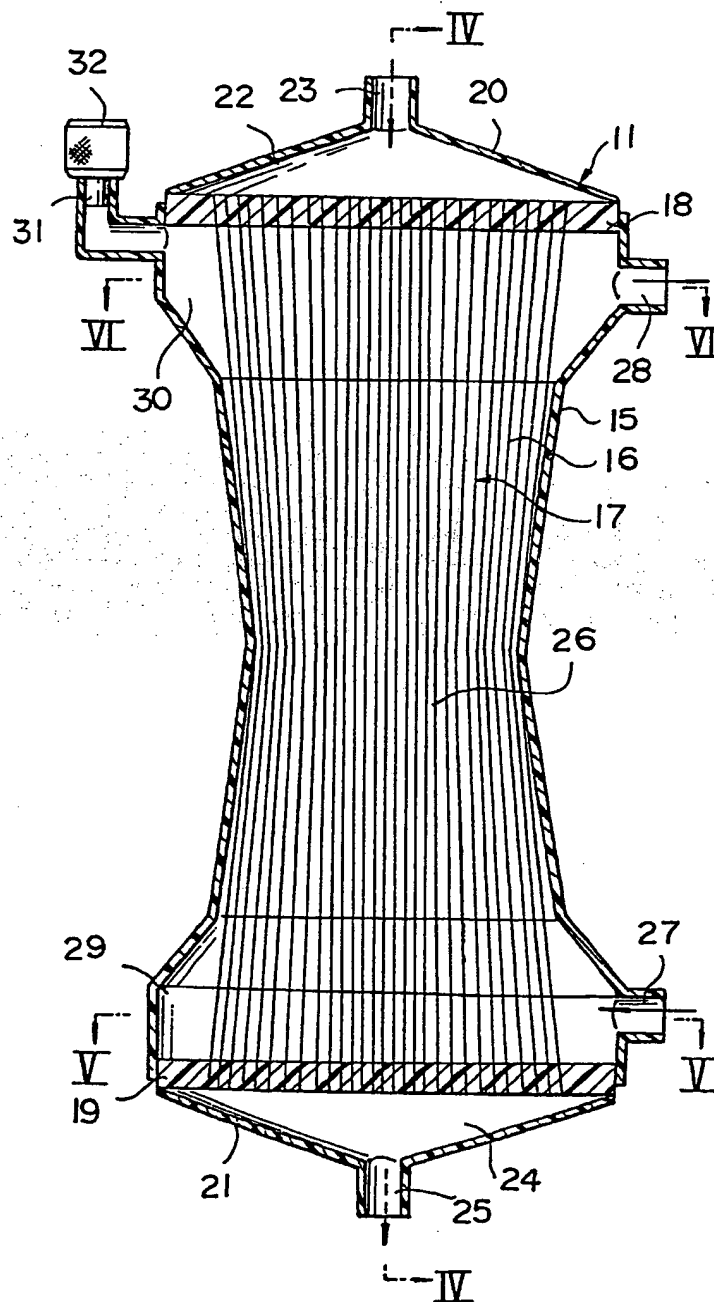


FIG. 5



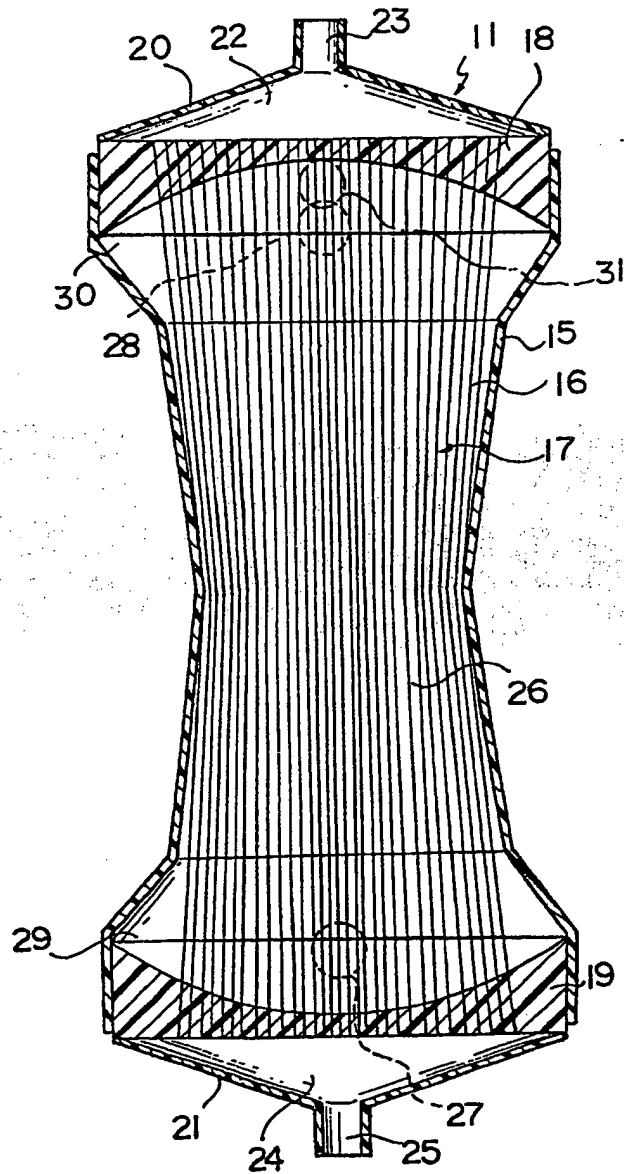
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FIG. 3



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FIG. 4



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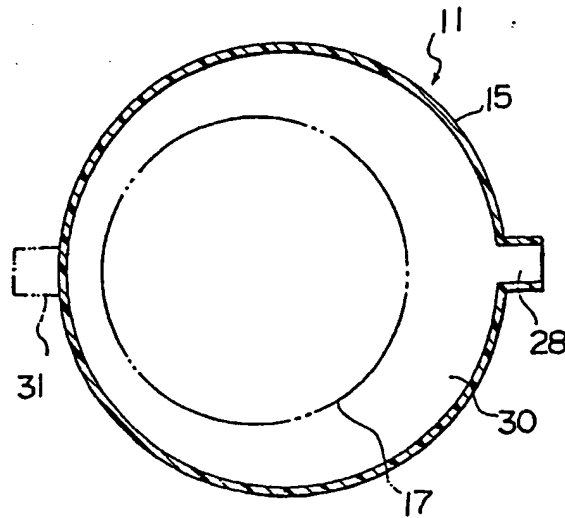
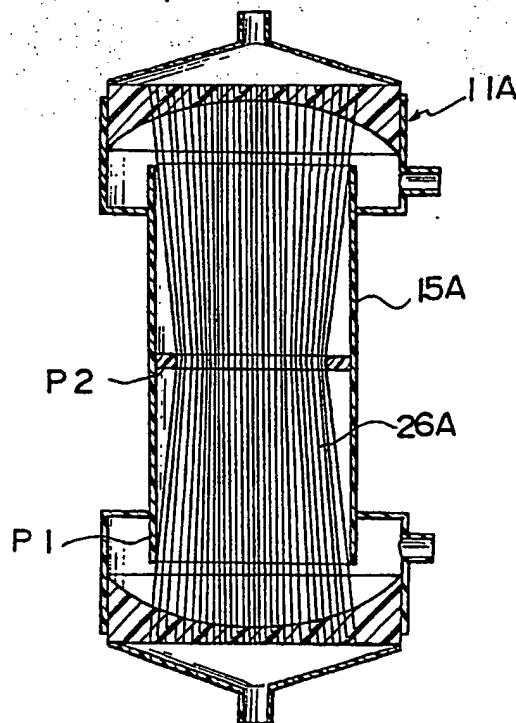


FIG. 6

FIG. 7



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FIG. 8

